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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/860,844	09/29/1997	SUSAN WEININGER	GP-100C1	9470
23557	7590	12/10/2004	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/860,844

Applicant(s)

WEININGER ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Exr. Int. Sum. proposal of 8/30/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28, 57 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 57, and 62-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, <u>8/30/04</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

It is acknowledged that the rejections of record in the previous office action, mailed 6/10/04, may have been overcome via a potential Examiner's amendment, however, further consideration of the instantly pending claims regarding possible other issues has revealed several significant issues that are summarized below that would not have been overcome via the potential amending, discussed in the Interview on August 30, 2004. It is also noted that said potential amendment, discussed on August 30, 2004, has neither been officially submitted nor entered as of the mailing of this office action.

Due to the newly applied rejections as summarized below, the finality of the previous office action, mailed 6/10/04, is hereby withdrawn.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Unfortunately, upon reconsideration, the following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 63 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been amended into claims 63-65 via the amendment, filed 3/29/04.

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In claims 63 and 65, in lines 4 and 5, respectively, the amendment added the limitation "all of" directed to a plurality of nucleic acid recognition units has neither been found as filed nor have applicants specifically pointed to written support for these amendments.

The NEW MATTER rejection, previously set forth in the Office action, mailed 6/10/04, directed to the amendment to claim 64 is hereby withdrawn due to several citations being found in the instant disclosure as filed directed to a TBA containing a protein nucleic acid recognition unit as an option.

VAGUENESS AND INDEFINITENESS

Claims 28, 57, and 62-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28, lines 4-6, cites the combined binding affinity of a TBA wherein it "does not bind" to "non-target" molecules. The TBAs listed in lines 10-12 of claim 28 are described in the specification on pages 53-55. On page 54, lines 13-19, each component therein is described as having "low affinity" for CNA and TBR sequences whereas the multimeric complex will have an extremely high affinity to "the now expanded TBR recognized by the multimeric complex". This description of affinity is different from the description regarding said TBAs in instant claim 28, lines 4-6, thus making claim 28 not commensurate in scope with the specification regarding affinity. Clarification of this conflict in scope is requested via clearer claim wording.

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The above target binding vs. not binding to non-target wording is also in claims 62-65, and claim 57 via dependence from claim 62, and is also not commensurate in scope with the specification for the same reasons as set forth in the above paragraph. Clarification via clearer claim wording is requested to remove this conflict in scope.

Lastly, it is reasonably expected that the respective segments in the claims such as NF-kB etc. in claim 62, last three lines, or binding subsegments of SEQ ID NO: 109 etc., as in claim 28, would have some affinity to their corresponding subsegments of a target double-stranded nucleic acid molecule which is targeted by the multimeric TBA molecule.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamarco et al. (P/N 5,453,362); taken in view of Jamieson et al. [Biochemistry 33:5689

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(1994)] and Desjarlais et al. [Proc. Natl. Acad. Sci (USA) 90:2256 (1993)]; taken further in view of Krizek et al. [J. Am. Chem. Soc. 113:4518 (1991)].

Lamarco et al. describes the practice of viral transcriptional control via regulators in the abstract. In column 6, lines 45-65, describe the usage of fusion proteins that find particular use in modulating gene expression. Therapy utilizing DNA binding interactions to modulate transcription factor is also described in column 8, lines 51-67. In column 1, line 24, through column 2, line 36, the viral gene modulation for treatment purposes is motivated as a use thereof. Therefore, the control and treatment of viral disease via gene expression modulation is described but without the formation of binding molecules for gene expression modulation.

Jamieson et al. describes the design of molecules which modulate or control gene expression on page 5689, first column, first 6 lines. The selection of zinc fingers with DNA-binding specificity is summarized in the abstract as the molecules designed for such control of gene expression for a specific DNA sequences.

Desjarlais et al. generalizes the zinc finger design as summarized in the abstract and left and right hand introductory columns on page 2256 as being usable for generic design of zinc fingers for DNA domains as desired. Desjarlais et al. summarizes therein the three finger motif of domains which correspond to recognition units of TBAs as instantly claimed. Desjarlais et al. also describes the specific ordering of recognition unit binding of zinc fingers on page 2260, left column, lines 1-31, as also a limitation of instant claims 64 and 65. Desjarlais et al. also describes the ligation of previously unligated recognition units in the sections entitled "A Consensus-Based Protein with

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Three Identical Zinc Fingers” and “Consensus-Based Proteins with Three Different Zinc Fingers” on pages 2257-2259 as also a limitation of instant claim 65. The multimeric binding tightness being directed to a target wherein the single component units do not bind thereto is not, however, described in either of Desjarlais et al. or Jamieson et al. It is also noted that Desjarlais et al. describes genes encoding the zinc finger proteins for intracellular gene expression of these proteins on page 2258, left hand column, which is also an option for protein delivery of the instant claims.

Krizek et al. is similarly directed to zinc finger design as summarized in the abstract. A summary of zinc finger development on page 4518, first column, describes various domains therein corresponding to each finger. On page 4518, first column, lines 1-15, the combined binding affinity of zinc fingers is discussed including a description that each single finger is “incapable of site-specific interactions with DNA”. This documents the characteristic of zinc finger proteins as containing recognition units wherein each such unit does not bind to target DNA as required also for the TBA recognition units as instantly claimed.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modulate gene expression for therapy as motivated in Lamarco et al. with DNA domain binding containing fusion proteins directed to specific DNA transcriptional control domains wherein zinc finger proteins provide designable fusion or TBA type multimeric proteins which bind to desired DNA domains for control of gene expression as summarized in the combination of Jamieson et al., Desjarlais et al, and Krizek et al. with the same characteristics as the TBA multimers thus resulting in

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the practice of embodiments of the instant claims with a reasonable expectation of success.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 65 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/407,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims include common embodiments in that the more limited now pending claim 65 is within the scope of claim 1 of said copending application where the plurality of nucleic acid recognition units may be all of them or a subset as reasonably interpreted for said claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 9, 2004

Ardin H. Marschel 12/9/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER